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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/500,324	06/28/2004	Francesco Paolini	07552.0031	8942

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EXAMINER	
WIEST, PHILIP R	
ART UNIT	PAPER NUMBER
3761	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	04/02/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/500,324	PAOLINI ET AL.	
	Examiner	Art Unit	
	Phil Wiest	3761	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on *21 December 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *26 and 28-50* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *26 and 28-50* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *21 December 2006* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Response to Amendment

In the response filed 12/21/06, Applicant amended claims 26, 28, 30, and 36-38, and canceled claim 27.

Drawings

The drawings were received on 12/21/06. These drawings are accepted.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

1. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

2. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

3. Claims 26-50 are rejected under 35 U.S.C. 103(a) as being unpatentable over Weitzel et al. (US 6561997) over Polaschegg (4,894,164), and further in view of Derek et al. (US 6,582,387).

4. With respect to Claim 26, Weitzel et al. disclose an apparatus for controlling an extracorporeal blood circuit comprising an access branch 58 that is connected to at least one blood treatment element 48 and a return branch 70 having one end connected to an outlet of at least blood treatment element 20. Both branches are connected to a patient 100 (see Figure 1). The apparatus comprises a sensor/control unit that is capable of "...precise control over fluid flow rate, pressure within the circuit, and temperature of fluid in the circuit" (Column 3, Lines 57-59), and a temperature regulating device (8, 34). Because "temperature ... can be precisely controlled" (Column 4, Lines 16-20), it is inherent that the apparatus comprises a control unit connected to the temperature regulating devices (8, 34). Furthermore, Weitzel et al. disclose that the heat exchanger 8 functions to keep the blood at a physiological temperature (Column 6,

Lines 16-19), thus functioning according to a first temperature (actual blood temperature) and a reference temperature (preferred physiological blood temperature).

Weitzel et al., however, does not disclose that the temperature sensor is located in the access branch, upstream of all blood treatment devices, nor does it disclose that the temperature regulating device 8 is located downstream of all blood treatment elements to form a heat exchanger directly before blood reenters the patent.

Polaschegg discloses a blood treatment apparatus comprising a temperature sensor 206 located in the access branch 220 and upstream of all blood treatment devices (see Figure 1). The temperature sensor 206 is used to record the temperature of the blood leaving the body for use as a reference temperature to be used by control unit 208 (Column 7, Lines 1-9). Therefore, it would have been obvious to one skilled in the art at the time of invention to combine the apparatus of Weitzel et al. with the temperature sensor placement of Polaschegg in order to measure the true temperature of blood leaving the body for use as a reference temperature for controlling the heat exchanger 8. By measuring the true blood temperature, the reference temperature/ desired blood output temperature will be closer to true physiological temperature of the patient rather than an estimated reference value.

Derek et al. discloses a blood treatment apparatus wherein a heat exchanger may be placed within the return tube 50 (Column 10, Lines 7-11), which is downstream of all blood treatment elements (see Figure 2). It is obvious that blood will cool down (or heat up, depending on the surrounding air temperature) when removed from the body to be treated in a blood treatment apparatus. Because of this, it would be desirable to

place the heat exchanger as far downstream and as close to the patient as possible, such that minimal temperature change occurs before blood is returned to the patient. Therefore, it would have been obvious to one skilled in the art at the time of invention to modify the blood treatment apparatus of Weitzel et al. with the heat exchanger placement of Derek et al. in order to minimize temperature change before blood reenters the body.

5. With respect to Claims 28 and 29, Weitzel et al. further disclose that the regulating device comprises a heat exchanger 8 that is connected to the circuit in order to control flow temperature, and a line 16 for conveying a fluid. The fluid being conveyed is capable of being heated to a temperature lying within a specified range about 37°C (Column 6, Lines 15-19), as per instant Claim 28. Regarding Claim 29, the heat exchanger can be "...at least partially surrounding any portion of the intake line" (Column 6, Lines 20-21).

6. With respect to Claim 30, the extracorporeal blood circuit is connected to a pump 52 which conveys fluid along the extracorporeal blood circuit, a line 70 for conveying fluid, and a sensor which detects the operating state of said pump. Regarding Claim 31, Weitzel et al. disclose expansion chambers 62 and 64 and a return branch 70 that is located downstream from the expansion chambers. Examiner interprets that "expansion chambers" are the same as the replacement fluid bags 62 and 64. Said replacement fluid bags serve to "...infuse [fluids] into the conduit 58 with a pump 56 to replace blood volume lost as a waste product 10" (Column 4, Lines 57-58).

7. With respect to Claims 32-35, Weitzel et al. disclose a blood treatment element formed by a filter 48, and at least one expansion chamber 62 and 64. Furthermore, Weitzel et al. disclose that the filter is a hemofilter 48, but that "...and blood treatment device can be used in place of the hemofilter 48. For example, but without limitation, a dialyzer or a plasma filter can be used to separate a filtrate component from the blood" (Column 5, Lines 10-13). Additionally, a dialyzer flowing from dialysis system 194 (see Figure 4) can be used to separate filtrate components from the blood (see Column 5, Line 10-13).

8. With respect to Claims 36 and 37, Weitzel et al. disclose that the control unit regulates the blood temperature of the extracorporeal blood in the line as a function of the blood temperature and the temperature of the body (37°C) (Column 6, Lines 16-19). This is inherent because Weitzel et al. disclose that the heat exchanger 8 functions to keep the blood at a physiological temperature (Column 6, Lines 16-19), thus functioning according to a first temperature (actual blood temperature) and a reference temperature (preferred physiological blood temperature). The controller will inherently function by calculating the difference between the actual temperature of the blood and a reference temperature, as per Claim 37. Furthermore, it is inherent that all sensors function by recording data at predetermined intervals of time, and a specific interval of time is not disclosed by Applicant. Said "predetermined intervals" are determined by the controller to which the sensor is attached, and are limited by the ability of the specific sensor.

9. With respect to Claims 38-43, Weitzel et al. disclose a control method for an extracorporeal blood circuit comprising an access branch 58 and a return branch 70 both of which being attached to at least one blood treatment element (20, 48) (see Figure 1). Both the access line and the return line are connected to the patient 100. The method comprises measuring and regulating a blood temperature in the extracorporeal blood circuit through the use of circuits that "...will provide tightly controlled pressure, flow, and/or temperature through the circuit" (Column 12, Lines 45-46). The blood temperature is regulated by the heat exchanger 8, which is located downstream from blood treatment element 48.

Weitzel et al., however, does not disclose measuring blood temperature using a sensor that is located in the access branch, upstream of all blood treatment devices, nor does it disclose heating the blood with a temperature regulating device 8 located downstream of all blood treatment elements.

Polaschegg discloses a blood treatment method comprising measusing blood temperature with a sensor 206 located in the access branch 220 and upstream of all blood treatment devices (see Figure 1). The temperature sensor 206 is used to record the temperature of the blood leaving the body for use as a reference temperature to be used by control unit 208 (Column 7, Lines 1-9). Therefore, it would have been obvious to one skilled in the art at the time of invention to combine the method of Weitzel et al. with the temperature sensor placement of Polaschegg in order to measure the true temperature of blood leaving the body for use as a reference temperature for controlling the heat exchanger 8. By measuring the true blood temperature, the reference

temperature/ desired blood output temperature will be closer to true physiological temperature of the patient rather than an estimated reference value.

Derek et al. discloses a blood treatment method and apparatus wherein a heat exchanger may be placed within a return tube 50 (Column 10, Lines 7-11), which is downstream of all blood treatment elements (see Figure 2). It is obvious that blood will cool down (or heat up, depending on the surrounding air temperature) when removed from the body to be treated in a blood treatment apparatus. Because of this, it would be desirable to heat blood at a point as far downstream and as close to the patient as possible, such that minimal temperature change occurs before blood is returned to the patient. Therefore, it would have been obvious to one skilled in the art at the time of invention to modify the blood treatment method of Weitzel et al. with the heat exchanger placement of Derek et al. in order to minimize temperature change before blood reenters the body.

10. Regarding Claims 39 and 40, the temperature of the blood is regulated in the heat exchanger 8 as a function of the actual blood temperature and the reference temperature. The heat exchanger 8 "...functions to keep blood at a physiological temperature such that any metabolic functions that the treatment device 20 carries out can be accomplished" (Column 6, Lines 16-19). Thus, the heat exchanger will correct the temperature of the blood according to the difference between the blood and the reference temperature. Heat will be added if this differential is positive, and removed if the differential is negative.

11. With respect to Claims 44-46, Weitzel et al. disclose a method wherein fluid is conveyed along the heat exchanger 8 through the connected tubing. The fluid is heated to within a specified range about 37°C. Blood is conveyed through the heat exchanger, as well as the rest of the circuit, by means of a pump. When the pump is not turned on, fluid in the heat exchanger will remain at a temperature equal to the reference temperature. Additionally, the Weitzel et al. discloses that the reference temperature is capable of being varied. The control system allows for "...precise control over fluid flow rate, pressure within the circuit, and temperature of fluid in the circuit" (Column 3, Lines 56-59).

12. With respect to Claims 47-50, Weitzel et al. disclose that the method of conveying fluid is used for a hemodialysis treatment that utilizes a hemofilter. Additionally, Weitzel discloses that any type of blood treatment device such as a dialyzer can be used to separate a filtrate component from the blood. This includes hemofiltration filters and hemodialysis filters through which blood and dialysate flow. See column 5, line 11 of the specification. The extracorporeal blood circuit also comprises expansion chambers 62 and 64 supplied with a replacement fluid (see column 4, lines 56-58).

Response to Arguments

13. Applicant's arguments with respect to claims 26-50 have been considered but are moot in view of the new ground(s) of rejection.

14. With respect to Claims 26 and 38, Applicant argues that Weitzel et al. does not disclose that the control unit regulates blood temperature as a function of the blood temperature and the temperature of the body, and that blood temperature is regulated as a function of the difference between the blood temperature and the reference temperature. Examiner disagrees. Weitzel et al. disclose that the heat exchanger 8 functions to keep the blood at a physiological temperature (Column 6, Lines 16-19). It is the examiner's opinion that said physiological temperature is equivalent to the reference temperature disclosed by Applicant, as it is the temperature that the heat exchanger tries to achieve. It is inherent that the heat exchanger is regulated as a function of the difference between the blood temperature and the reference temperature because heating will occur if the temperature of the blood is lower than the reference temperature (because there is a difference between the blood and reference temperatures, blood will have to be heated until the temperatures are equal). Furthermore, a "control unit" may be anything that controls the temperature of the fluid. In this case, Weitzel clearly discloses that temperature is precisely controlled to be kept at a physiological temperature (Column 6, Lines 16-19).

15. Applicants other arguments are in reference to the amended claims, and are discussed in the rejection above.

Conclusion

16. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL.** See MPEP

§ 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

17. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Phil Wiest whose telephone number is (571) 272-3235. The examiner can normally be reached on 8:30am-5pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tatyana Zalukaeva can be reached on (571) 272-1115. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

PRW
3/27/07

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